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CERTIFICATE OF MAILING BY FIRST CLASS MAIL (37 CFR 1.8) Applicant(s): JOSEPH C. SALAMONE ET AL.			Docket No. P02389
Serial No. 09/738,808	Filing Date DECEMBER 15, 2000	Examiner K. M. THORNTON	Group Art Unit 1744

Invention: **PREVENTION OF PRESERVATIVE UPTAKE INTO BIOMATERIALS**

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Joseph C. Salamone et al.	)	
	)	Examiner: K. M. Thornton
Serial No.: 09/738,808	)	
	)	Group No.: 1744
Filed: December 15, 2000	)	
	)	Docket No: P02389
Title: PREVENTION OF PRESERVATIVE UPTAKE INTO BIOMATERIALS	)	

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Appeal Brief – Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313, on February 6, 2004.

Rita D. Vacca

APPEAL BRIEF
(37 C.F.R. 1.192)

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313

Sir:

By Notice of Appeal filed on or after September 15, 2003, applicants appeal the Final Rejection in the above-identified application dated April 8, 2003, and submit this Brief (in triplicate) in support thereof. A Petition requesting a three (3) month extension of time under 37 C.F.R. 1.136 within which to file Appellant's brief under 37 C.F.R. 1.192 is enclosed herewith. Authorization to charge the fee under 37 C.F.R. 1.17(a)(3) and 1.17(c) to Deposit Account No. 02-1425 is provided in the transmittal letter accompanying this Appeal Brief.

I. REAL PARTY IN INTEREST

The real party in interest in this appeal is Bausch & Lomb Incorporated, as evidenced by the Assignment recorded at Reel 011388/Frame 0117.

II. RELATED APPEALS AND INTERFERENCES

Applicants are not aware of any other appeals or interferences that will directly affect, be directly affected by, or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

A. Total Number of Claims in Application

Claims in the application are 1-23.

B. Status of All the Claims

Claims 20-22 are withdrawn from consideration.

Claim 8 is cancelled.

Claims 1-7, 9-19 and 23 are currently pending.

Claims 1-7, 9-19 and 23 stand rejected.

C. Claims on Appeal

Claims 1-7, 9-19 and 23 form the basis of this appeal.

IV. STATUS OF AMENDMENTS

The status of the amendment filed January 8, 2003 was entered and an explanation of how the new or amended claims would be rejected was provided in the Office Action of April 8, 2003 and confirmed in the Advisory Action of July 15, 2003.

V. SUMMARY OF INVENTION

Generally, the claimed invention provides a method for treating biomaterials that have the ability to reversibly sorb cationic antimicrobial agents. Such biomaterials appear to accumulate antimicrobial agents when they are in contact with a solution having an antimicrobial concentration sufficient to drive sorption of the antimicrobial agents to the biomaterials. Upon such biomaterial contact with an aqueous solution having lower antimicrobial concentrations, the antimicrobial agents are desorbed. In the case of contact lenses, over a period of time the positively charged, ionically bound antimicrobial agents are released from the biomaterial forming the lens through displacement by endogenic ions in the tear film and can cause tissue irritation.

The method of the present invention inhibits the ability of a biomaterial to sorb cationic antimicrobial agents. The subject method comprises treating the surface of an anionic hydrogel biomaterial with a cationic polysaccharide.

As discussed at **p. 4, line 16** of the specification, the method for treating a hydrogel biomaterial **p. 8, line 9**, of the present invention comprises contacting the surface of the hydrogel biomaterial with a cationic polysaccharide **p. 4, line 28**, to inhibit the ability of the hydrogel

biomaterial to sorb cationic antimicrobials **p. 5, line 4**. The surface of the biomaterial may be treated to provide a net anionic charge **p. 5, line 1,** which may include the use of a linking agent **p.5, line 8,** or the surface of the biomaterial may carry a net anionic charge without a treatment step **p. 5, line 1**. Regardless of the technique employed, the cationic polysaccharide is retained on the surface of the biomaterial through ionic interactions, hydrogen-bonded interactions, hydrophobic interactions and/or covalent interactions **p. 5, line 30**. Such interactions occur between oppositely charged ionic groups between the biomaterial and an aqueous solution containing the cationic polysaccharide **p. 6, line 2**.

Suitable cationic polysaccharides may include cationic starch, cationic dextran, cationic chiosan, cationic locust bean gum, cationic gum tragacanth, cationic curdlan, cationic pullulan and cationic scleroglucan **p. 6, line 29**. The cationic charge on the cationic polysaccharide is derived from ammonium groups, quaternary ammonium groups, sulfonium groups and/or phosphonium groups **p. 6, line 7**. The negative charge on the surface of the biomaterial may be derived from carboxylate groups, sulfonate groups, phosphate groups, phosphonate groups, sulfate groups and/or phosphinate groups **p. 6, line 4**. Methods of the present invention are useful for biomaterials formed as ophthalmic contact lenses or intraocular lenses, **p. 6, line 24**, manufactured from silicone hydrogel material **p. 8, line 11**. Such a contact lens may be useful as an extended-wear contact lens suitable for periods of continuous wear for about 7 to 30 days **p. 8, line 26**.

Independent claim 1 defines a method for treating a hydrogel biomaterial comprising contacting the surface of a hydrogel biomaterial with a cationic polysaccharide to inhibit the ability of the hydrogel biomaterial to sorb cationic antimicrobials.

Methods of the present invention may include treating the surface of the biomaterial to provide a net anionic charge or treating with a linking agent or having a biomaterial with a surface net anionic charge without treatment. Such methods are specifically claimed in dependent claims 2-4. Dependent claims 5-14 and 23 further define interactions between the cationic polysaccharide and with the surface of the biomaterial of claim 1. Dependent claims 15-18 further define the composition and/or form of the biomaterial of claim 1. Dependent claim 19 further defines the cationic polysaccharide of claim 1.

VI. ISSUES

The issues raised by this appeal are:

Whether claims 1, 3, 5-6, 9-11, 14-17 and 23 were improperly rejected as unpatentable under 35 U.S.C. 102(b) over Ellis et al., (U.S. Patent Number 5,401,327);

Whether claims 1-7, 9-16 and 19 were improperly rejected as unpatentable under 35 U.S.C. 102(b) over Ellis et al., (U.S. Patent Number 4,321,261); and

Whether claim 18 was improperly rejected as unpatentable under 35 U.S.C. 103(a) over Ellis et al., (U.S. Patent Number 5,401,327) or Ellis et al., (U.S. Patent Number 4,321,261).

VII. GROUPING OF CLAIMS

Claims 1, 5, 9-14 and 19 stand or fall together.

Claims 15-18 stand or fall together.

Claims 2-4, 6, 7 and 23 stand or fall together.

VIII. ARGUMENTS

Claims 1, 3, 5-6, 9-11, 14-17 and 23 were improperly rejected as unpatentable under 35 U.S.C. 102(b) over Ellis et al., (U.S. Patent Number 5,401,327).

A. The Cited Reference

Ellis et al., disclose the use of an ophthalmic solution including polyethylene oxide (PEO) components composed of a hydrophobic core having at least three carbon atoms and at least three hydrophilic polyethylene oxide chains attached to the core. The core of these "star-like" components provides a means, when adsorbed on a surface, to achieve a high, localized density of PEO chains across the surface to increase the hydrophilicity thereof and thereby provide protein resistance.

B. Claims 1, 5, 9-14 and 19

Applicants submit that no *prima facie* case of anticipation has been established. Ellis et al. does not disclose each and every element of the present invention. The present invention as claimed provides a method **for inhibiting the ability of a hydrogel biomaterial to sorb cationic**

antimicrobial agents through the use of simple cationic polysaccharides. The subject method as disclosed and claimed differs significantly from the method disclosed by Ellis et al., relating to "star-like" components for treating lenses to repel **protein deposits from forming on the surface** of treated lenses. It is the position of the Office that "treatment of similar surfaces with similar materials would inherently yield the same results". To the contrary, the material of the present invention is not the same or similar to the star-like component containing material of Ellis. Hence, the unique method of the present invention for inhibiting the ability of a biomaterial to sorb cationic antimicrobials as disclosed and claimed differs significantly from the patented invention described by Ellis et al. For these reasons, a *prima facie* case of anticipation has not been established based on Ellis et al. Withdrawal of the rejection of claims 1, 5 and 9-11 and 14 under 35 U.S.C. 102(b) over Ellis et al. is respectfully requested.

C. Claims 15-18

Dependent claims 15-18 more specifically define the method of claim 1 with regard to the biomaterial. For the same reasons stated in section VIII.B., *supra*, no *prima facie* case of anticipation has been established against these claims.

As the cited reference fails to disclose each of the methods of claims 15-17, the rejection is improper. Accordingly, reversal of the rejection of claims 15-17 is requested.

D. Claims 2-4, 6, 7 and 23

Dependent claims 2-4, 6, 7 and 23 more specifically define the method of claim 1 with the addition of a net anionic charge, negative charge or a linking agent treatment step to the biomaterial. For the same reasons stated in section VIII.B., *supra*, no *prima facie* case of anticipation has been established against these claims.

As the cited reference fails to disclose each of the additional limitations of claims 3, 6 and 23 the rejection is improper. Accordingly, reversal of the rejection of claims 3, 6 and 23 is requested.

Claims 1-7, 9-16 and 19 were improperly rejected as unpatentable under 35 U.S.C. 102(b) over Ellis et al., (U.S. Patent Number 4,321,261).

E. The Cited Reference

Ellis et al. disclose a contact lens solution for wetting, soaking and lubricating hard contact lenses. The lens solution includes an ionic polymer of **cationic or anionic charge**, preservatives, viscosity modifiers, lubricity agents, soaking and cleaning agents and buffers. The ionic polymer in the solution serves to interact with an oppositely charged lens surface to form a polyelectrolyte complex. The polyelectrolyte complex has an equal amount of cations and anions. The electrically neutral complex exists as an ionically cross-linked hydrogel that is effective in retaining water of hydration (Col.3, lines 5-9).

F. Claims 1, 5, 9-14 and 19

Applicants submit that no *prima facie* case of anticipation has been established. To the contrary, claims of the present application provide a method for inhibiting the ability of a biomaterial to **sorb (lens internal polymer matrix)** cationic antimicrobials through the use of cationic polysaccharides. The subject method as disclosed and claimed differs significantly from the disclosure of Ellis et al., relating to methods for inhibiting protein **adhesion (lens external polymer matrix)** to the surface of a contact lens through the use of anionic or cationic polymers. Accordingly, the unique method of the present invention that unexpectedly inhibits the ability of a biomaterial to sorb cationic antimicrobial agents as disclosed and claimed differs significantly from the patented invention disclosed by Ellis et al. It is unexpected that the subject method would be effective in inhibiting the ability of a biomaterial to sorb cationic antimicrobial agents since an electrical bilayer exists. Negative ions beneath the cationic polysaccharides could serve as a bridge to transport cationic antimicrobials and allow the same to sorb into the biomaterial. Unexpectedly, this is not the case. For these reasons, a *prima facie* case of anticipation has not been established based on Ellis et al. Withdrawal of the rejection of claims 1, 5, 9-14 and 19 under 35 U.S.C. 102(b) over Ellis et al. is respectfully requested.

G. Claims 15-18

Dependent claims 15-18 more specifically define the method of claim 1 with regard to the biomaterial. For the same reasons stated in section VIII.F., *supra*, no *prima facie* case of anticipation has been established against these claims.

As the cited reference fails to disclose each of the methods of claims 15 and 16, the rejection is improper. Accordingly, reversal of the rejection of claims 15 and 16 is requested.

H. Claim 2-4, 6, 7 and 23

Dependent claims 2-4, 6, 7 and 23 more specifically define the method of claim 1 with the addition of a net anionic charge, negative charge or a linking agent treatment step to the biomaterial. For the same reasons stated in section VIII.F., *supra*, no *prima facie* case of anticipation has been established against these claims.

As the cited reference fails to disclose each of the additional limitations of claims 2-4, 6 and 7 the rejection is improper. Accordingly, reversal of the rejection of claims 2-4, 6 and 7 is requested.

Claim 18 was improperly rejected as unpatentable under 35 U.S.C. 103(a) over Ellis et al., (U.S. Patent Number 5,401,327) or Ellis et al., (U.S. Patent Number 4,321,261).

I. The Cited References

Disclosures of Ellis et al., U.S. Patent Number 5,401,327 are described in section VIII.A., *supra*.

Disclosures of Ellis et al., U.S. Patent Number 4,321,261 are described in section VIII.E. *supra*.

J. Claims 1, 5, 9-14 and 19

Applicants submit that no *prima facie* case of obviousness has been established. Claims of the present application provide a method for inhibiting the **ability of a biomaterial to sorb** cationic antimicrobials. Such is unique regardless of the end use of the biomaterial whether it be an extended wear contact lens or any other medical device. The subject method as disclosed and claimed differs significantly from the teachings of Ellis et al., '327 or Ellis et al., '261. Methods suitable for repelling proteins from the surface of a lens are not necessarily suitable for inhibiting sorption of cationic antimicrobials into the interior matrix of a biomaterial. Likewise, methods suitable for forming ionically cross-linked hydrogels that are effective in retaining water of hydration are not necessarily suitable for inhibiting sorption of cationic antimicrobials into the interior matrix of a biomaterial. Accordingly, each of the limitations of the subject invention is not taught by the unrelated methods of Ellis et al. '327 or Ellis et al. '261. Accordingly, the unique method of the present invention for inhibiting the ability of a biomaterial to sorb cationic antimicrobials as disclosed and claimed is not obvious in view thereof.

K. Claims 15-18

Dependent claims 15-18 more specifically define the method of claim 1 with regard to the biomaterial. For the same reasons stated in section VIII.J., *supra*, no *prima facie* case of obviousness has been established against claim 18.

As the cited references fail to teach each of the limitations of claim 18, the rejection is improper. Accordingly, reversal of the rejection of claim 18 is requested.

L. Claim 2-4, 6, 7 and 23

Dependent claims 2-4, 6, 7 and 23 more specifically define the method of claim 1 with the addition of a net anionic charge, negative charge or a linking agent treatment step to the biomaterial. For the same reasons stated in section VIII.J., *supra*, the present invention as claimed is not obviousness in view thereof.

In light of the foregoing arguments, applicants request that the outstanding rejections be reversed and that pending claims 1-7, 9-19 and 23 be allowed.

IX. APPENDIX OF CLAIMS INVOLVED IN THE APPEAL

Claim 1 (Previously amended): A method for treating a hydrogel biomaterial comprising contacting the surface of said hydrogel biomaterial with a cationic polysaccharide to inhibit the ability of the hydrogel biomaterial to sorb cationic antimicrobials.

Claim 2 (Original): The method of claim 1 further comprising treating the surface of said biomaterial to provide a net anionic charge on said surface before contacting said surface with said cationic polysaccharide.

Claim 3 (Original): The method of claim 1 wherein the surface of said biomaterial carries a net anionic surface charge and wherein the method includes no intermediate treatment step to modify the surface charge before binding said polysaccharide to the surface of said biomaterial.

Claim 4 (Original): The method of claim 2 wherein said surface treating step further comprises contacting said surface with a linking agent.

Claim 5 (Original): The method of claim 1 wherein said binding step further comprises retaining said cationic polysaccharide on the surface of said biomaterial through at least one selected from the group consisting of ionic interactions, hydrogen-bonded interactions, hydrophobic interactions and covalent interactions.

Claim 6 (Original): The method of claim 5 wherein said ionic interactions are between oppositely charged ionic groups between the biomaterial and an aqueous solution containing the cationic polysaccharide.

Claim 7 (Original): The method of claim 6 wherein the negative charge on the biomaterial is derived from at least one selected from the group consisting of carboxylate groups, sulfonate groups, phosphate groups, phosphonate groups, sulfate groups, and phosphinate groups.

Claim 8 (Cancelled)

Claim 9 (Original): The method of claim 5 wherein said hydrogen-bonding interactions occur between hydrogen-bond accepting surfaces and hydrogen-bond donating solutions, or through hydrogen-bond donating surfaces and hydrogen-bond accepting surfaces.

Claim 10 (Original): The method of claim 9 wherein said hydrogen-bond accepting groups are selected from the group consisting of pyrrolidone groups, N,N-disubstituted acrylamide groups and polyether groups.

Claim 11 (Original): The method of claim 10 wherein said polyether groups are poly(ethylene glycol) or poly(ethylene oxide).

Claim 12 (Original): The method of claim 9 wherein said hydrogen-donating groups are selected from the group consisting of carboxylic acids, sulfonic acids, sulfuric acids, phosphoric acids, phosphonic acids and phenolic groups.

Claim 13 (Original): The method of claim 5 wherein said hydrophobic interactions occur through hydrophobic sites on the biomaterial surface interacting with hydrophobic groups on the cationic polysaccharide.

Claim 14 (Original): The method of claim 5 wherein said covalent interactions exist between the biomaterial surface and the water-soluble cationic polysaccharide such that the cationic polysaccharide is bound to the biomaterial surface.

Claim 15 (Original): The method of claim 1 wherein said biomaterial is an ophthalmic lens.

Claim 16 (Original): The method of claim 15 wherein said ophthalmic lens is a contact lens.

Claim 17 (Original): The method of claim 1 wherein said biomaterial is a silicone hydrogel material.

Claim 18 (Previously amended): The method of claim 17 wherein said silicone hydrogel material is an extended-wear contact lens suitable for periods of continuous wear for about 7 to about 30 days.

Claim 19 (Original): The method of claim 1 wherein the cationic polysaccharide is selected from the group consisting of cationic starch, cationic dextran, cationic chiosan, cationic locust bean gum, cationic gum tragacanth, cationic curdlan, cationic pullulan and cationic scleroglucan.

Claims 20 – 22 (Withdrawn)

Claim 23 (Previously added): The method of claim 6 wherein the cationic charge on the cationic polysaccharide is derived from at least one selected from the group consisting of ammonium groups, quaternary ammonium groups, sulfonium groups, and phosphonium groups.

Should there be any questions regarding this communication, please feel free to contact the undersigned at (636) 226-3340.

Respectfully submitted,

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